Pre-Application Conference

Day 2

Welcome
&
Agenda

Day 2 Agenda

- Systems Requirements
- Systems/Testing Timeline
- Recap / Important Dates
- Wrap Up

Systems Requirements

Karen Jackson
Enrollment & Eligibility System

Kim Miegel
Payment & Financials System

Tom Dudley
Price Comparison

Laura Minassian–Kiefel
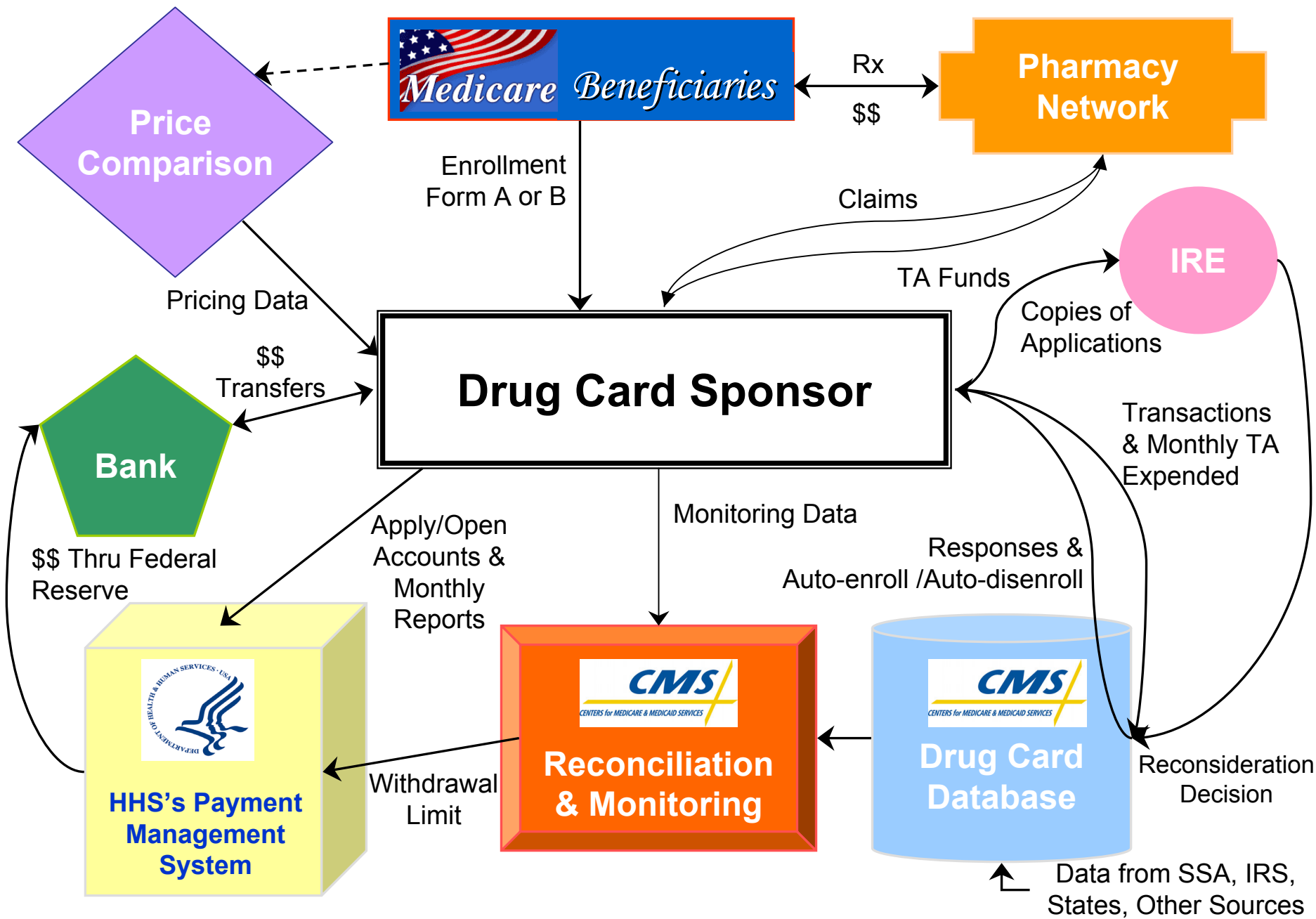*Reporting & Performance Monitoring*
Centers for Medicare & Medicaid Services

Systems Requirements

- **This morning we will:**
  - **Describe CMS' Systems & Interfaces**
    - Enrollment & Eligibility Transactions
    - Payment & Financials
    - Price Comparison Website
    - Monitoring & Reporting
  - **Explain Infrastructure Requirements**
    - Connectivity
    - Access & User IDs
    - Internal System Requirements
    - Security
  - **Explain the "Go Live" Requirements**
  - **Explain the Testing Plan**

CMS' Systems & Interface

- **CMS is developing the systems with which sponsors will interface, through approved telecommunication lines.** (see graphic on next slide)

- **Sponsors interface with CMS' systems to:**
    - Draw and report federal funds used
    - Submit performance monitoring data
    - Submit data for Price Comparison Website
    - Submit and receive electronic transactions for drug card and transitional assistance (TA) enrollment and disenrollments

- **CMS will fund and facilitate the installation of a T-1 connection and furnish Connect:Direct software, if needed, to each sponsor.**

Price Comparison

Medicare Beneficiaries

Pharmacy Network

Rx
$$

Enrollment Form A or B

Claims

TA Funds

IRE

Copies of Applications

Pricing Data

$$ Transfers

Drug Card Sponsor

Transactions & Monthly TA Expended

Bank

Apply/Open Accounts & Monthly Reports

Monitoring Data

Responses & Auto-enroll /Auto-disenroll

$$ Thru Federal Reserve

HHS's Payment Management System

Withdrawal Limit

CMS
CENTERS for MEDICARE & MEDICAID SERVICES

Reconciliation & Monitoring

CMS
CENTERS for MEDICARE & MEDICAID SERVICES

Drug Card Database

Reconsideration Decision

Data from SSA, IRS, States, Other Sources

6

Enrollment & Eligibility System Drug Card Database

- **Purpose**
  - Verify a beneficiary's eligibility for the discount drug card and transitional assistance program
  - Track enrollments / disenrollments
  - Implement exclusivity provision
  - Track transitional assistance balances
  - Data repository and reporting
  - Support reconsideration process
- **Sponsors submit and receive periodic (up to daily) electronic batch transactions, using the connectivity provided by CMS.**
- **Sponsor's internal systems must be able to generate and edit the CMS prescribed file format and record layout.**

Enrollment & Eligibility System Drug Card Database - Continued

- **Types of Transactions Generated by Sponsors**
  - Initial Enrollment
    - Discount Drug Card Only
    - Discount Drug Card & TA
    - TA Enrollment following Enrollment in Discount Drug Card
  - Special Election Period (SEP) Enrollments
  - Annual Coordinated Enrollment Period Enrollments
  - Disenrollments
    - Voluntary
    - Involuntary
  - Monthly TA Expenditure Amount
- **Types of Transactions Generated by CMS**
  - Enrollment confirmation / denial, including indicator for notification letter
  - Auto-enrollments following reconsideration decision
  - Auto-disenrollment

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Enrollment & Eligibility System Drug Card Database - Continued

- **Transaction record layouts and file specifications will be posted on the CMS Drug Card website.**
  - Data elements will include those collected on the application and other transaction specific elements.
  - CMS plans to use national standards as applicable.
- **CMS will send confirmation upon receipt of files.**
- **Transaction Response Time Frames**
  - 24 hours for drug card only enrollments and most other transactions
  - 72 hours for transitional assistance enrollments
- **CMS' Eligibility Verification Process**
  - CMS receives enrollment transaction from sponsor
  - CMS' Enrollment & Eligibility System checks data sources (SSA, IRS, States, CMS' systems, other sources as determined) and makes decision
  - CMS notifies sponsor of decision

Batch Transactions

- **Sponsors must segregate transitional assistance enrollment transactions from drug card only enrollment transactions.**

- **We are planning for receipt of up to two batch files per day per sponsor.**
  - One batch file with TA enrollments
  - One batch file with Discount Drug Card Only enrollments and all other transactions

- **Sponsors must perform consistency edits prior to sending file to CMS.**

- **Unreadable files will be rejected.**

- **CMS will process up to a total of 30,000 transactions daily per sponsor.**

- **CMS will respond to each file provided by a sponsor with a response file, plus one additional file for auto-generated enrollments and disenrollments.**

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File Specifications & Record Layout

- **We will post final systems requirements, file specifications and the transaction record layouts on the Drug Card website by the end of December.**

- **Help desk support will be provided for the testing and validation activities for sponsors.**

Questions?

- Please post your questions on the bulletin boards provided throughout the room.

- If additional questions arise after the conference, please submit them through the feedback link found on the discount drugs website at www.cms.hhs.gov.

Payment & Financials

Kim Miegel

Centers for Medicare & Medicaid Services

Payment & Financials: Questions to Be Answered

- How to obtain payment for TA members?

- What data must be submitted for payment?

- What is the payment reconciliation process?

How to Obtain Payment?

- For TA members only
- Up to $30 enrollment fee
- $600 subsidy
- Via Payment Management System (PMS)

How to Obtain Payment?

- Sponsor accesses PMS website to complete account paperwork.
- Sponsor provides EIN to CMS.
- CMS certifies accounts in PMS.
- Sponsors establish connectivity to PMS.

How to Obtain Payment?

- Sponsor submits payment requests to PMS.

- PMS transmits to the Treasury.

- Treasury makes same-day funds transfer to sponsor accounts.

What Data Must Be Submitted for Payment?

- Sponsor submits payment request to PMS.

- Sponsor submits quarterly expenditure report (SF-272) to PMS.

What Data Must Be Submitted for Payment?

- Sponsors submit monthly TA expended information to CMS Drug Card Database.

- Sponsors submits monthly certified report of funds drawn and expended for TA to CMS.

19

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What Is the Payment Reconciliation Process?

- CMS compares TA enrollment and expenditure information to PMS monthly withdrawal reports.

- CMS compares TA enrollment and eligibility data to Sponsor's monthly and quarterly expenditure data.

What Is the Payment Reconciliation Process?

- CMS will reconcile differences from the comparisons due to timing issues between the data sources.

- Sponsors must reconcile remaining differences.

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Break

Additional System Requirements Session to follow at ?.

- **Price Comparison**
- **Reporting & Performance Monitoring**
- **Transaction Requirements**
- **Infrastructures Requirements**
- **Testing Plan**
- **"Go Live" Requirements**

Price Comparison on www.medicare.gov

Thomas Dudley, MS, RN

Beneficiary Education

Centers for Medicare & Medicaid Services

Price Comparison Timeline

- January 30, 2004 - Perspective discount card sponsors will submit electronic test data files with their applications.

- March 2004 – The endorsed discount drug card sponsors will submit electronic data files with their signed contracts.

Price Comparison Timeline (continued)

- April 2004 - General Card Sponsor Program information (e.g. contact information) will be posted on www.medicare.gov.

- April 30, 2004 - The Price Comparison website is scheduled to be launched on www.medicare.gov .

Price Comparison and PDAP on www.medicare.gov

Price Comparison <u>Will</u>:

- Be merged into the existing Prescription Drug and Other Assistance Programs (PDAP) database design.

- Only be accessible through the PDAP section of <u>www.medicare.gov</u>.

- Pricing info.will be provided for Brand name, Generic, and Mail-order prescriptions.

Price Comparison and PDAP on www.medicare.gov(cont.)

Price Comparison <u>Will</u>:

- List the maximum contracted negotiated price for each drug at the pharmacy level for each program.

- Drug card sponsors will be able to update their program's drug pricing information weekly.

Price Comparison and PDAP on www.medicare.gov

Price Comparison
Will Not:

- Provide pricing information for any other program type.
- Provide pricing information for Managed Care Discount Card Programs.

- Accommodate enrollment (individuals will need to contact the program sponsors to enroll).

Price Comparison Data File Transfer

- **All program contact information will be sent to CMS.**

- **All drug pricing information will be sent directly to CMS' contractor, DestinationRx, Inc.**

  - FTP with secure signatures
  - Each sponsor will have their own password protected user area.
  - Files will be fixed length.

Data Submission and Updates

- Data for Price Comparison will be updated on a weekly basis. (Only data changes will be submitted)

- All card sponsors will submit their electronic drug pricing data files directly to CMS' contractor for Price Comparison, DestinationRx, Inc.

- All Data must be submitted by **Midnight PST** on **Wednesday** of each week.

- DestinationRx, Inc. will process and display the submitted data by **12:01 AM EST** on **Monday** of each week.

Price Comparison Data Requirements

CARD SPONSOR PROGRAM FORMAT

	Field	Description
1	Program Sponsor ID	Program Sponsor ID (CMS assigned)
2	Program Sponsor Name	Program Sponsor Name
3	Plan ID	Plan ID (CMS assigned)
4	Plan Name	Plan Name
5	Program Type	Program Eligibility Type (Income level)
6	Service Area	Service Area (CMS Specified)
7	Address Line 1	Address Line 1
8	Address Line 2	Address Line 2
9	City	City
10	State	State
11	Zip Code	Zip
12	Phone	Toll Free Phone Number
13	TTY Phone	TTY Phone Number
14	Annual Enrollment Fee	Annual Enrollment Fee
15	Customer Service Hours	Hours of Operation for Customer Service

DRUG PRICING FORMAT		
	Field	Description
1	Program Sponsor ID	Program Sponsor ID (CMS Assigned)
2	Plan ID	Plan ID (CMS Assigned)
3	NDC Number	National Drug Code
4	Pharmacy Number	Pharmacy NABP Number
5	Pharmacy Chain Number	Pharmacy Chain Number
6	Price	Price Per Pill

PROGRAM SPONSOR CONTACT INFORMATION

	Field	Description
1	Program Sponsor ID	Program Sponsor ID (CMS Assigned)
2	Plan ID	Plan ID (CMS Assigned)
3	First Name	Contact First Name
4	Last Name	Contact Last Name
5	Title	Contact Title
6	Phone	Contact Phone Number
7	Address Line 1	Address Line 1
8	Address Line 2	Address Line 2
9	City	City
10	State	State
11	Zip Code	Zip
12	Email	Contact Email
13	Alt. Phone	Alternate Contact Phone
14	Alt. Email	Alternate Email Address
15	Alt. Address Line 1	Alternate Address Line 1
16	Alt. Address Line 2	Alternate Address Line 2
17	Alt. City	Alternate City
18	Alt. State	Alternate State
19	Alt. Zip Code	Alternate Zip
20	Tech. Contact First Name	Technical Contact First Name
21	Tech. Contact Last Name	Technical Contact Last Name
22	Tech. Contact Phone	Technical Contact Phone
23	Tech. Contact Email	Technical Contact Email
24	Alt. Tech. Contact First Name	Alternate Technical Contact First Name
25	Alt. Tech. Contact Last Name	Alternate Technical Contact Last Name
26	Alt. Tech. Contact Phone	Alternate Technical Contact Phone
27	Alt. Tech. Contact Email	Alternate Technical Contact Email

Questions?

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Reporting & Performance Monitoring of the Drug Card

Laura Minassian-Kiefel

Centers for Medicare & Medicaid Services

Overview

- **Application Requirements**

- **Reporting Requirements**

- **Record Retention Requirements**

Application Requirements

- Certify and Comply with Reporting Routinely to CMS on Major Features of Program

- Certify Based on Best Knowledge, Information and Belief that Reported Information Is Accurate, Complete, Truthful and Supportable

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Application Requirements - Continued

- Describe Method Used to Adhere to All Reporting Requirements (Attachment 6)

- Describe Procedures to Ensure CMS Will Be Informed of Any Material Modifications to Program.

  Examples Are:
  - **Network Changes**
  - **Price Increases Not Due to ⬆ AWP**
  - **Change in Customer Service Practices**

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Reporting Requirements

- **Due 10th Business Day Following Reporting Period by 5:00 PM ET**
  - Unless Immediate or Weekly Reporting Specified
  - Exact Due Dates Will Be Posted on www.cms.hhs.gov

- **Report Information into CMS' HPMS or Enrollment & Eligibility System**
  - Access instructions will be posted on the CMS Drug Card website

Reporting Requirements - Continued

- **Every Submission Requires**

  - **Certification**

    Based on Best Knowledge, Information and Belief the Reported Information Is Accurate, Complete, Truthful and Supportable

  - **Sponsor ID**

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Immediate Reporting Requirements

- Material Modifications to Program

- Aberrancies or High Utilization and Spend Patterns
  - **By Zip Code**
  - **Drugs on DEA Control Schedule II-IV**

Weekly Reporting Requirements

- Updated Price Files for Price Comparison Website If Prices/Other Information Changes
  - Discussed Earlier

- Rationale for Any Price Increases Besides ⬆ AWP
  - N/A Week of November 15, 2004

Monthly Reporting Requirements

- Report Data for Month Only

- Aggregated Grievance Data
  - # Filed Grievances By Category
  - # Resolved
  - # Resolved that Favor Enrollees

Monthly Reporting Requirements - Continued

- **Prescription Data**
  - Total # Prescriptions
  - Average # by Enrollee

- **Certification that Aberrancies or High Utilization and Spend Patterns Were Not Found**

Monthly Reporting Requirements - Continued

- Transitional Assistance (TA) Reimbursement
  - Each TA Enrollee's
    - **HIC #**
    - **Name**
    - **Sex**
    - **Date of Birth**
    - **$ Spent From Subsidy Balance**

Quarterly Reporting Requirements

- Report Data for Quarter Only

- Customer Service Information
  - **% CSR Time Manning Phones/Responding to Inquiries**
  - **Total # Calls**
  - **# & % Calls Answered within 30 Seconds**
  - **# & % Calls Abandoned from Automated Queue**
  - **Call Center Business Hours**

Quarterly Reporting Requirements - Continued

- Customer Service Information - Continued
  - **% Business Hours When Call Center Not Available**
  - **Average Days to:**
    - **Process New Members**
    - **Provide New or Replacement Discount Cards**
    - **Respond to Written Correspondence**
    - **Fulfill Mail Order Request (No Intervention Required)**
    - **Fulfill Mail Order Request (Intervention Required)**

Quarterly Reporting Requirements - Continued

- **Price Concessions and Pass-Throughs to Enrollees**
  - **% Total Manufacturer Price Concessions Passed Through to Enrollees**
  - **Average $ Amt of Manufacturer Price Concessions per Script by Manufacturer**
  - **% Total Retail Pharmacy & % Total Mail Order Price Concessions Passed through to Enrollees**
  - **Average Negotiated Price per Script Across All Drugs Produced by Each Manufacturer**

Quarterly Reporting Requirements - Continued

- Price Concessions and Pass-Throughs to Enrollees - Continued
  - **Average $ Amt of Pharmacy Price Concessions per Drug Card Script by All Retail Pharmacy & Mail Order**
  - **Average $ Amt of Manufacturer Price Concessions per Brand Script**
  - **Average $ Amt of Manufacturer Price Concessions per Generic Script**
  - **Average $ Amt of Pharmacy Price Concessions per Brand Script**

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Quarterly Reporting Requirements - Continued

- **Price Concessions and Pass-Throughs to Enrollees - Continued**
  - Average $ Amt of Pharmacy Price Concessions per Generic Script
  - Range / Average Negotiated Price by NDC (Including by Manufacturer or Generics) at a Given Point in Time;
  - Average / Range of Dispensing Fees

Guidelines for Maintaining Certain Records

- Guidelines Discussed Earlier
  - Keep All Records on All Areas for Six Years After Program Ends

- Oversight May Entail a Review of Claims and Grievance Log Data

Claims Data Elements of Particular Interest

- Sponsor ID
- Enrollee Name
- Enrollee HIC #
- 11 Digit NDC
- Negotiated Price w/o Dispensing $
- Enrollee Co-Pay $
- Sales Tax $
- Generic Indicator

- U&C Price w/o Dispensing $
- AWP
- DEA # of Physician
- Rx #
- NABP # of Pharmacy
- Date Rx Filled

Format for Maintaining Grievance Logs

- Sponsor ID
- Enrollee Name
- Enrollee HIC #
- Date Received
- Date Decided
- Disposition
- Category

Grievance Log Category Requirements

- Enrollment

- Disenrollment

- Marketing

- Benefits/Access

- Pricing/Co-Pay

- Customer Service

- Confidentiality

- Pharmacies

- Other

Questions?

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Technical Requirements

Karen Jackson

Centers for Medicare & Medicaid Services

Telecommunications & Connectivity to CMS

- **CMS will fund and facilitate installation of a T-1 connection and furnish Connect:Direct software, if needed, to each sponsor.**

- **Applicants must submit a <u>CMS Connectivity Request</u> to Scott Nelson, as specified in the solicitation ASAP.**

  - Your need for a T-1 line to CMS and/or Connect:Direct software is communicated to CMS using this form.

  - Your ability to start accepting enrollments in your Drug Card Program is dependent, among other things, upon successful establishment of an approved connection with CMS.

  - Report immediately any change in your request or installation issues to the Discount Drug Card IT Help Desk ASAP.

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Telecommunications & Connectivity to CMS - Continued

- **CMS will start the T-1 installation process during the solicitation application and review period.**
  - AT&T Global Network Services is CMS' contractor for set-up and maintenance of the T-1 lines.
  - AT&T will work directly with applicants that have requested connectivity.
  - The T-1 installation process generally takes 45 days from request.
  - T-1 connectivity, using Connect:Direct, must be tested prior to announcement of endorsed sponsors so that programs can begin end-to-end testing in April.
  - See the Testing Plan.
- **CMS will purchase Connect:Direct licenses for applicants who need it for the Drug Card Program.**
  - We will follow up with applicants to gather all of the details needed for the Connect:Direct purchase and delivery. Delivery is expected by mid-February.

CMS User IDs

- **Applicants must request CMS User IDs to conduct systems testing and gain access to CMS applications in advance of endorsement.**
  - Use Drug Card Specific form found on the CMS Drug Card website.
  - User IDs will be provided for transmission of data files for the enrollment and eligibility system, HPMS and Price Comparison.
  - Access to appropriate applications will be issued sequentially.
  - The testing plan will have dates for future submission of forms for user IDs.
  - Forms should be submitted to the contact listed in the Solicitation.
- **When endorsed, sponsors will submit a CMS Data Use Agreement in order to receive live data.**

Solicitation Requirement for Sponsors' Internal Systems

- **Solicitation specifies requirements for:**
    - Tracking enrollments & subsidy amounts
    - Point of sale claims processing
    - Reduction of medication errors & adverse drug reactions
    - Tracking & reporting drug pricing
    - Draw down of federal funds
    - Reporting usage of funds & other data
    - Linking call center to 1-800-Medicare
    - Tracking and reporting grievances
    - Generate transactions, including enrollment/disenrollment & monthly subsidy expenditures
    - Accept auto-enrollments and auto-disenrollments
    - Information and outreach & inquiries
    - Protecting privacy & security of records

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Security Requirements

- **Provide your attestation that appropriate administrative, technical and physical safeguards are in place to protect the privacy of protected health information.**

- **If you are unable to provide this attestation, provide your plan for coming into compliance with the specifications of the Security Rule, as required in Section 3.5.11 of the solicitation.**

- **Referring to the Information Security Program references as provided by the National Institute of Standards and Technology (NIST), http://csrc.nist.gov, may assist you in describing your efforts to implement reasonable security measures.**

Solicitation References

- **System Requirements are listed throughout the Solicitation. The following are key sections for focus, though not to be considered a comprehensive list.**
  - **Section 1.3.2 – Transitional Assistance Administration**
  - **Section 2.2 – Testing & Go Live Criteria**
  - **Section 2.7.1 – CMS Connectivity**
  - **Section 2.7.2 – CMS User ID**
  - **Section 3.5 – Sponsor's Internal Systems**
  - **Section 3.5.1-3.5.3 – Transactions**
  - **Section 3.5.4 & 3.5.5 – Payment & Reporting**
  - **Section 3.5.10 & 3.5.11 – Security**
  - **Section 3.6 & Attachment 6 – Reporting**

"Go Live" Requirements

- **Before an endorsed sponsor will be approved to start marketing and accepting enrollments, the sponsor must have successfully completed end-to-end testing or established an CMS-approved method of fulfilling all transaction and data requirements.**

Testing Plan

- **CMS will issue system requirements, a Testing Plan and Testing Check List. These documents will be posted on the Drug Card website by the end of December.**
- **Sponsor must conduct internal testing using CMS furnished test files.**
  - CMS will make test files available in January.
  - The files will be posted on the Drug Card website.
  - The files will be in text format with comma delimiters.
  - The test files will include sample input records of each type and correct and incorrect output records expected for every input file.
  - Sponsors must successfully complete internal testing and submit Testing Check List before beginning end-to-end testing with CMS.

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Testing Plan - Continued

- **Telecommunication Testing**
  - Active line testing will be scheduled and performed by AT&T.
  - Testing of connectivity using Connect:Direct will be planned, scheduled and performed by both the CMS Test Manager and the Sponsor's technical point-of-contact.
- **End-to-End Testing**
  - Beginning in April, endorsed sponsors who have successfully completed internal and telecommunication line testing will be scheduled for end-to-end testing.
  - Sponsors will submit a signed Check List to request end-to-end testing.

Testing Time Line

- **December 29, 2003**
    - Sponsor system requirements & specifications posted on the CMS Drug Card website.
    - Sponsors submit CMS Connectivity Request.
    - AT&T begins processing connectivity requests.
- **January 15, 2004**
    - Test data and test package available.
- **February 2004**
    - Connect:Direct software available.
- **March 21, 2004**
    - Sponsor internal testing complete.
    - Submit Testing Check List to CMS.
- **March 24, 2004**
    - Connectivity testing begins.

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"Getting There"

- **Maintaining open communications between CMS and sponsors will help ensure timely implementation.**

- **CMS Discount Drug Card IT Help Desk will be available for answers to any system related questions.**

- **Additional systems requirements information not presented today will be posted on the CMS Discount Drug Card website as indicated.**

CMS Discount Drug Card IT Help Desk & Assistance for Sponsors

- **CMS is establishing a Drug Card IT Implementation Help Desk**
  - Track implementation milestones
  - Route issues for resolution
  - Coordinate specialized help desks
    - AT&T for T-1 Lines
    - CMS/OIS for Connect:Direct software
    - Enrollment & Eligibility Transaction Problems
    - CMS' contractor for submitting pricing data
    - HHS' PMS system
    - HPMS Technical Assistance
      - 1-800-220-2028 or hpms@nerdvana.fu.com
      - CMS Contact: Don Freeburger, dfreeburger@cms.hhs.gov, 410-786-4586

Questions?

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Wrap Up

- Closing & Thank You
- Success together!!

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